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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,390	01/22/2004	Koral Embil	EDKO-001	2411

Louis C. Paul
9th Floor
730 Fifth Avenue
New York, NY 10019

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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12/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/761,390

Applicant(s)

EMBIL ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14, 16-26, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 16-26, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of claims, response and declaration dated 10-19-07 is acknowledged.

Claims 15, 27 and 28 are canceled. New claims 29 and 30 have been added.

Claims 1-14, 16-26 and 29-30 are pending.

Response to Arguments

Applicant's arguments, filed 10-19-07, have been fully considered and are persuasive. The declaration filed by Dr. Robert Lochhead has been fully considered. Pursuant to the declaration and applicants' arguments, the rejections of record have been withdrawn. However, a new rejection has been applied showing that the release of active agent from a porous polymer is recognized as a function of the interaction of the solvent and a carrier.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15726 (submitted on PTO-1449, hereafter WO 26) in view of US 5879716 (Katz).

WO 26 teaches a composition for acne treatment comprising clindamycin and benzoyl peroxide in the form of a kit, separately maintained in different containers (page 9, L 25-35 and Example compositions on pages 11-12). Benzoyl peroxide composition comprises a polymer and both compositions have water and hence meet the claimed

limitations. WO 26 fails to state the lipophilicity exclusively, the compositions of two components (table 1) are both water based and do not appear to vary in their hydrophilicity or lipophilicity and teaches adjusting the viscosity of the compositions for better release and activity.

Katz teaches a composition comprising benzoyl peroxide that is impregnated inside porous solid particles or microspheres, prepared by suspension polymerization of monomers (abstract, col. 3, L 65+). Katz teaches that once the microspheres are formed they are impregnated with benzoyl peroxide, introduced as a solution. Katz further teaches that the composition containing the benzoyl peroxide impregnated microspheres further contain carriers or vehicles and states that when liquid vehicles are used and the impregnant is a solution of an active agent in a solvent, the solvent and the vehicle must be immiscible so that outward diffusion of the active agent will not be accelerated by mutual diffusion between the solvent and vehicle (col. 8, L 1-16). Katz teaches employing appropriate combinations of polar solvents and a non-polar vehicle or vice-versa. Katz also suggests adding other actives such as salicylate etc (col. 7, L 49-54). Accordingly, it would have been obvious for an ordinary skill in the art at the time of the instant invention was made to prepare formulations of benzoyl peroxide and also other actives in combination with other active agents in the formulation of WO by preparing the active agents in an appropriate solvents to impregnate them in a porous polymer and also choose an appropriate carriers such that the release of the active agent is released in appropriate amounts from the porous polymer and at the same time the porous polymer permit the outward diffusion of the active agent at a controlled rate,

suggested by Katz. Even though Katz does not explicitly state "lipophilicity", a skilled artisan would have understood that the release of the active agent (in high or low concentration) is related to the diffusion of the active agent out of the polymer and is affected by the carrier.

2. Claims 3-14, 16-26 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15726 (submitted on PTO-1449, hereafter WO 26) in view of US 5879716 (Katz) as applied to claims 1, 2, and 23-24 above, and further in view of Wester et al (hereafter Wester, J. American Academy of Dermatology) and EP 306236 (hereafter EP), both submitted on PTO-1449.

WO 26 described above, fails to teach the claimed microsphere polymer of the instant claims. WO also fails to teach the combination of active agents other than benzoyl peroxide and clindamycin. Katz, discussed above, teaches a porous polymer impregnated with benzoyl peroxide.

Wester teaches controlled release of benzoyl peroxide from a porous microsphere polymeric system for reducing topical irritancy. Wester compared the difference between the release of the above compound from a polymeric composition and non-polymeric composition (freely dispersed drug) and observed that the compound of significantly better absorbed through the skin when released from the former system and also reduced irritation (abstract, lines bridging pages 720-721 and

results on page 722-723). The polymeric system of Wester is the same as the instant micro sponge.

EP also teaches controlled release of several skin care and hair care active agents such as benzoyl peroxide, salicylic acid, minoxidil etc., from a composition containing a micro sponge polymeric system (the same micro sponge as that claimed in the instant invention). In particular, EP (as well as Wester) teaches the treatment of acne with benzoyl peroxide. For the various active agents of EP, see pages 2-5, 7, page 12, L 40-45 and examples and on page EP teaches a number of combinations of the active agents.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the micro sponge polymeric delivery material of Wester or EP as a polymer in the composition of WO26, either in one or both compartments, because both Wester and EP suggests that the porous polymeric material forms a continuous network open to the exterior particles, permitting outward diffusion of the impregnated active agents in a controlled fashion. Further, EP suggests that the polymer is suitable for a wide variety of active agents and their combinations and hence including any combination of active agents, in the teachings of WO26, that are suitable for acne treatment would have been obvious for a skilled artisan. Further, incorporating more than two active agents in different dispensing containers (in the teachings of WO26), and adjusting the openings or closures, so that the active agents can be dispensed separately would have been obvious from the teachings of EP because EP suggests more than two active ingredients for the same treatment such as acne.

Specification

The use of a number of trademark compounds has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Examiner notes that the compounds are appropriately designated as trademark, but does not have generic names.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

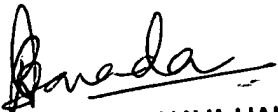
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/761,390
Art Unit: 1615

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
December 20, 2007


LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER